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10/537,288	06/01/2005	Bertrand Piot	271640US0PCT	1851
	7590 10/06/2008 LON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.		EXAMINER	
1940 DUKE STREET			GEORGE, KONATA M	
ALEXANDRIA, VA 22314		ART UNIT	PAPER NUMBER	
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			10/06/2008	ELECTRONIC

### Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)	
	10/537,288	PIOT, BERTRAND	
Office Action Summary	Examiner	Art Unit	
	KONATA M. GEORGE	1616	
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with the c	correspondence address	
A SHORTENED STATUTORY PERIOD FOR REPLEWHICHEVER IS LONGER, FROM THE MAILING ID.  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by stature Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION  .136(a). In no event, however, may a reply be tind  d will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 25.	is action is non-final. ance except for formal matters, pro		
Disposition of Claims			
4)  Claim(s) 19,20,22-40 and 42-52 is/are pendir 4a) Of the above claim(s) is/are withdra 5)  Claim(s) is/are allowed. 6)  Claim(s) 19,20,23-32,36-40 and 42-52 is/are 7)  Claim(s) 22 and 33-35 is/are objected to. 8)  Claim(s) are subject to restriction and/ Application Papers 9)  The specification is objected to by the Examin	rejected.  or election requirement.		
10) The drawing(s) filed on is/are: a) ac Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	e drawing(s) be held in abeyance. Sec ction is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
<ul> <li>12) Acknowledgment is made of a claim for foreig</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documer</li> <li>2. Certified copies of the priority documer</li> <li>3. Copies of the certified copies of the priority documer</li> <li>application from the International Burea</li> <li>* See the attached detailed Office action for a list</li> </ul>	nts have been received. nts have been received in Applicationity documents have been received au (PCT Rule 17.2(a)).	on No ed in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal F 6)  Other:	ate	

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#### **DETAILED ACTION**

Claims 19, 20, 22-40 and 42-52 are pending in this application.

### **Action Summary**

Any rejections of record that are not repeated below are considered withdrawn.

### Allowable Subject Matter

The indicated allowability of claims 19, 20, 23-30, 32-40 and 42-52 is withdrawn.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19, 20, 23-32, 36-40 and 42-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ajinomoto Co. Inc. (EP 0 538 764 A1).

## Determination of the scope and content of the prior art (MPEP §2141.01)

Ajinomoto Co. Inc. teaches in Table 6, page 8, a composition comprising a physiologically acceptable medium (36.95% of pure water), at least one alkyl parahydroxybenzoate (ethyl and propyl para-hydroxybenzoate 0.03% and 0.02% respectively), and at least on lipophilic amino acid derivative (5.0 % of ester D as defined as N-lauroyl-N-methyl-β-alanine as described in preparation example 4, page 5). It is taught that after components 1 and 2 where mixed a powder of adrenocortical hormone was added.

## Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Ajinomoto Co. Inc. does not the teach use of a wax in the composition or the concentrations of the particles or the claimed ratio of the para-hydroxbenzoate to the lipophilic amino acid ester.

# Finding of prima facie obviousness Rational and Motivation (MPEP §2142-2143)

Although Ajinomoto Co. Inc. does not teach the use of waxes in the composition by way of an example, the specification teaches that waxes can be used. Page 3, lines 19-24 of Ajinomoto teach a group of compounds that can be used as a substitute for an oily base, such as animal and vegetable oils, waxes (beeswax or carnauba wax), mineral oil, silicone oils, vaseline, synthetic oils, etc. It is the position of the examiner

that all of the compounds listed could be used interchangeably with a reasonable expectation of achieving the same results. Since, table 6 teaches that Vaseline can be incorporated into the composition; one of ordinary skill in the art would have been motivated to substitute a wax for the Vaseline in the preparation to achieve the desired results of the composition. Table 7 teaches that the drug can be added ad lib to the O/W emulsion base. It is the position of the examiner that adding the drug ad lib allows one of ordinary skill in the art to add as little or as much of the powdered drug necessary to elicit a response of the drug.

With respect to the claimed ratio this determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific ratio of the para-hydroxbenzoate to the lipophilic amino acid ester of the as employed by applicant in the instant case.

#### Allowable Subject Matter

Claims 22 and 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the amino acid ester as isopropyl-N-lauroylsarcosinate as taught in claim 22 and the prior art does not teach the solid particles selected from silk fibers, cotton fibers, wool fibers, etc. as taught in claims 33-35.

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Conclusion

Claims 19, 20, 23-32, 36-40 and 42-52 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Konata M. George, whose telephone number is 571-

272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to

Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone

numbers for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

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/Konata M. George/

Primary Examiner, Art Unit 1616